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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,749	08/12/2002	Constance E Brinckerhoff	DC-0155	2413

26259 7590 11/15/2004

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,749	BRINCKERHOFF ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed September 21, 2004. Currently, claims 1-5 are pending. Claims 3-5 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election with traverse of Group I, (Claims 1-2) in the paper filed September 21, 2004 is acknowledged.

The response asserts that MPEP 803 is clear that the inventions must be shown to be independent or distinct and a burden on the examiner. It is noted that since this application was filed as a 371 of a PCT, this application applies the unity of invention standards set forth in the MPEP and discussed in the previous action. Unity of invention requires neither independent or distinct inventions nor requires a burden. Unity of invention requires that there is no special technical feature which links the inventions. As discussed previously, the prior at teaches the MMP-1 polymorphism of an insertion of a G. Thus, this is not a special technical feature over the art.

The response appears to assert that Claim 3 is drawn to a method for detecting a polymorphism. This argument has been thoroughly reviewed, but is not found persuasive because the claim is drawn to a kit comprising products. The products may be any means for detecting MMP-1 polymorphism. As previously discussed, this encompasses the full length gene, probes and primers which were disclosed in the prior art. Thus, this is not a special technical feature over the prior art.

Claims 3-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed September 21, 2004.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 3-5 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application is a 371 application of PCT/US99/26610, filed November 10, 1999 and priority to provisional application 60/110,266, filed November 30, 1998.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded

hyperlink and/or other form of browser-executable code. See MPEP § 608.01 (see page 8).

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of diagnosing a matrix metalloproteinase-1 related disease in a patient comprising detecting in the patient MMP-1 containing the Ets transcription factor binding site single nucleotide polymorphism.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written

description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The claims are drawn to detecting "the Ets transcription factor binding site single nucleotide polymorphism." The specification teaches that an insertion of a G at position -1607. It is noted that the specification does not explicitly state the position of the insertion in SEQ ID NO: 3. Since SEQ ID NO:s are all positive numbers, it is unclear what position –1607 encompasses. A quick search of SEQ ID NO: 3 reveals there are approximately 8 sites of AAGAT which would enable an Ets transcription factor binding site (positions 540;1030;1930;2760;2790;2820;3170 and 3260). The specification does not appear to provide any guidance as to which of these sites is analyzed. Applicants are reminded that no new matter may be entered into the claims.

Since the instant claims fail to specifically set forth "the Ets transcription factor binding site single nucleotide polymorphism," the claims do not appear to be limited to any particular polymorphism. It is clear from the post filing date art that several polymorphisms exist in the MMP-1 promoter. Jurajda et al. (Molecular and Cellular probes, Vol. 16, pages 63-66, 2002) teaches a polymorphism at –519A/G in the promoter. Thus, it is clear that there are multiple polymorphisms within this MMP-1

promoter. With respect to claims which encompass allelic variations. As provided in Example 11 of the Written Description Guidelines, no common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a single polymorphism at –1607 (of an undisclosed sequence) alone is insufficient to describe the genus. There is no description of the mutational sites that exist in nature and no description of the structure of any strictly neutral alleles. The general knowledge in the art concerning variants does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

In the event that applicants wish to amend the claim to specifically be directed to the –1607 polymorphism and the specification supports a description of the polymorphism in terms of a SEQ ID NO:, this rejection may be easily overcome be adding such language.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 1-2 are drawn to a method of diagnosing a matrix metalloproteinase-1 related disease in a patient comprising detecting in the patient MMP-1 containing the Ets transcription factor binding site single nucleotide polymorphism.

The claims are broadly drawn to detecting any metalloproteinase-1 related disease by detecting "the Ets transcription factor binding site polymorphism" which has not be specifically set forth in the claims in any patient.

The invention is an class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

The art supports the unpredictability of the broadly drawn claims.

First, the claims fail to clearly set forth "the Ets transcription factor binding site polymorphism." While the specification appears to only discuss a polymorphism which is located at –1607 of a sequence with an insertion of a G to generate a AAGGAT sequence. Jurajda et al. (Molecular and Cellular probes, Vol. 16, pages 63-66, 2002) teaches a polymorphism at –519A/G in the promoter. Thus, it is clear that there are multiple polymorphisms within this MMP-1 promoter.

Also, the claims are directed to matrix metalloproteinase-1 related disease. The specification art does not clearly teach which disease are encompassed by "matrix metalloproteinase-1 related disease." The art teaches analysis of many diseases and a single nucleotide polymorphism in the promoter of the matrix-metalloproteinase-1 gene. Lee et al. (Scand J. Rheumatol. Vol. 32, pages 235-239, 2003) teaches the genotype distribution of the MMP-1 promoter did not differ between rheumatoid arthritis patients

and control subjects. The promoter polymorphism in the MMP-1 promoter may not play an important role in the susceptibility of RA, but the polymorphism may be related to clinical phenotypes. Lee further suggests that there may be ethnic differences in polymorphisms. Lee compared their data with the published data on Caucasians and noticed significant difference in MMP-1 polymorphisms between Caucasians and Koreans (page 238, col. 1).

Constantin et al. (J. of rheumatology, Vol. 29, No. 1, pages 15-20, January 2002) teaches that in a study of 103 patients with early RA, the MMP-1 allele and genotype frequencies did not differ between RA patients and controls. Constantin teaches that the results do not support the hypothesis of an association between this particular polymorphism in the MMP-1 gene promoter and susceptibility to or severity of RA.

Moreover, the art teaches the lack of association of a single nucleotide polymorphism in the promoter of the MMP-1 gene in Czech women with pregnancy-induced hypertension (Jurajda et al. Gynecol Obstet Invest. Vol. 52, pages 124-127, 2001).

Zhang et al. (Stroke, Vol. 32, pages 2198-2202, 2001) teaches that no significant difference was detected between the patient and control groups in relation to subarachnoid hemorrhage.

Johnson et al. (Genes and Immunity, vol. 2, pages 273, 2001) teaches the lack of association of a functionally relevant single nucleotide polymorphism with MMP-1 and systemic sclerosis (scleroderma).

Louka et al. (Scand J. Gastroenterol. Vol. 8, pages 931-935, 2001) teaches celiac disease is not associated with a functional polymorphism in MMP-1 gene promoter.

Matsumura et al. (J. Cancer Res. Clin. Oncol., Vol. 130, pages 259-265, 2004) teaches that the frequency of 1G/2G genotypes in gastric cancer patients was similar to those in controls (p=0.57). The degree of tumor invasion, the presence of lymph node metastasis and clinical stage showed no significant association with the SNP. Matsumura teaches that the presence of 2G allele in the MMP-1 promoter did not enhance the risk of gastric cancer, however it may be involved in differentiation of gastric cancer.

Moreover, the specification teaches that analysis of the 1G/2G polymorphism was examined in 100 controls and several tumor cell lines. The prior art establishes that cell lines are not appropriate means for examining associations with diseases. Specifically, Dermer *et al.* (Biotechnology Vol. 12, March 1994, p. 320) teach that cell lines are a poor representation of malignancy because they have survived crisis and have adapted an immortal life in culture, and thus has been enabled to survive in its artificial environment. Dermer *et al.* state that "the petri dish cancer is really a poor representation of malignancy, with characteristics profoundly different from the human disease."

More specifically, Sidransky et al. (US Pat. 5,856,094, January 1999) teaches a comparison between cell lines and primary tumors. In the case of p16, the rate of homozygous deletions ranged from 40-60% of breast cancer cell lines, however, neither homozygous deletions or point mutations are typically observed in primary breast carcinomas (col. 2, lines 10-15). Therefore, presence of homozygous deletions in cell lines is not indicative of primary tumors.

Moreover, Teng et al. (US Pat. 5,989,885, November 1999) teaches that discovery of mutations in cancer cell lines requires determination of whether the lesions occur in primary or metastatic tumors (col. 39, lines 49-55). Despite detection of

mutation in cancer cell lines, no sequence variants were detected in 45 primary breast tumor specimens (col. 39, lines 53-56). Teng states that the MKK4r mutations in these lines were possibly generated wile these cells were cultured in vitro (col. 40, lines 5-10).

Guidance in the Specification.

The specification teaches that MMP-1 promoter DNA may contain 1 G at position –1607 or 2 Gs at that location. The full length DNA sequence of MMP-1 with only 1 G at position –1607 is depicted in SEQ ID NO: 3. As discussed above, the disclosure of –1607 does not clarify the location of the polymorphism analyzed in the specification. A review of SEQ ID NO: 3 revealed numerous sequences where this polymorphism may occur. The specification fails to provide the background for this polymorphism. A quick search of SEQ ID NO: 3 reveals there are approximately 8 sites of AAGAT which would enable an Ets transcription factor binding site (positions 540; 1030; 1930; 2760; 2790; 2820; 3170 and 3260). The specification does not appear to provide any guidance as to which of these sites is analyzed. Applicants are reminded that no new matter may be entered into the claims.

The specification provides an analysis of this 1G/2G difference in the leukocyte clone sequence and the A2058 melanoma sequence (page 8). 100 control DNAs derived from CEPH pedigrees and several tumor cell lines were analyzed. The occurrence of 2G homozygotes in the CEPH controls was determined to be approximately 30%. In the tumor cell lines, it was 62.5% ($p<0.0001$)(page 8).

Moreover, the claims are directed to patient. Patient is not limited to humans, but rather encompass dogs, cats, monkeys, for example. There is no discussion, disclosure or analysis regarding the presence of the polymorphism and association with MMP-1 related diseases in any patient.

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses

Working Examples

The specification has no working examples of sampling of patients with matrix metalloproteinase-1 related diseases to determine frequencies in the populations.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied before the skilled artisan could use the claimed invention as broadly as claimed.

First, the specification and the claims fails to specifically identify "the Ets transcription factor binding site single nucleotide polymorphisms" by structure. The specification discusses an insertion of a G to create a AAGGAT sequences. A review of SEQ ID NO: 3 revealed numerous sequences where this polymorphism may occur. The specification fails to provide the background for this polymorphism. A quick search of SEQ ID NO: 3 reveals there are approximately 8 sites of AAGAT which would enable an Ets transcription factor binding site (positions 540; 1030; 1930; 2760; 2790; 2820; 3170 and 3260). The specification does not appear to provide any guidance as to which of these sites is analyzed.

Second, the claims are broadly drawn to diagnosing a MMP-1 related disease. The specification fails to teach the genus of diseases encompassed within the claim. The specification contemplates cancer and rheumatoid arthritis, however, the genus of MMP-1 related diseases appears to be much broader. The post-filing date art makes it clear that some diseases are associated with MMP-1 and some diseases are not associated with MMP-1 promoter 2G polymorphism. The skilled artisan would be required to perform additional experimentation for each of the MMP-1 diseases to determine whether an association is present prior to using the claimed method. Since some diseases are and some diseases are not associated with the polymorphisms, it is unpredictable which diseases are associated with the polymorphisms without further unpredictable and undue experimentation. This would require significant inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The analysis provided in the specification is directed at 100 controls and tumor cells lines. As discussed above, tumor cell lines are not representative of tumors from patients. Given the teachings in the specification and the art, there is no correlation that may be accurately inferred between cell lines and patients tumors.

Moreover, the art and the specification teaches that the 2G polymorphism is present in frequencies of about 30%. Thus, based upon the claim language, the skilled artisan would incorrectly diagnose a patient with a MMP-1 disease 30% of the time. In the cases where an association exists, the art appears to be directed to an increased predisposition, but the art fails to teach a diagnostic based upon the presence of a single nucleotide polymorphism.

Further, Lee specifically points out that there is an ethnic difference in the 2G/1G polymorphism. Lee compared the data with the published data on Caucasians and

noticed a significant difference in MMP-1 polymorphisms between Caucasians and Koreans (pages 238, col. 1). The genotype distribution of the MMP-1 promoter differed significantly between Caucasian and Korean control subjects (p=0.00038)(pages 238, col. 1). Therefore, it is clear that an association determined in a single population would not be indicative of an association in all populations. The skilled artisan would be required to perform additional experimentation to determine whether the disease and the polymorphism is associated. As evidenced by the art, it is unpredictable that any polymorphism is associated with any particular disease in any particular population.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the art teaches a lack of association between a polymorphisms and numerous MMP-1 diseases, the lack of specific guidance as to which MMP-1 polymorphism is analyzed, the ethnic differences and the broad inclusion of any patient, and diagnostics. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-2 are indefinite because it is unclear whether the claims are drawn to a method of diagnosing a MMP-1 disease in a patient or whether the claims are directed to detecting a MMP-1 polymorphism. The preamble of the claim requires diagnosing a MMP-1 related disease, however the final step of the method requires detecting polymorphism.

B) Claims 1-2 are indefinite over the recitation "the Ets transcription factor binding site single nucleotide polymorphism" because "the Ets transcription factor binding site single nucleotide polymorphisms" lacks proper antecedent basis. Moreover, it is unclear how this polymorphism is defined since there is no structural guidance relating to the polymorphism.

.Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Aho et al. (Eur. J. Biochem. Vol. 247, pages 503-510, July 1997).

As set forth in the 112/2nd rejection above, it is unclear whether the method requires diagnosing a MMP-1 related disease or merely detecting a polymorphism. The rejection below is provided in the event that the claims are drawn to a method of detecting the polymorphism.

Aho et al. (herein referred to as Aho) teaches a method of detecting a nucleic acid with a Ets transcription factor binding site polymorphism. Aho teaches a mutation of the first Ap-1 site resulted in major reduction of the basal level of the MMP-1 promoter activity, supporting the notion that the Ap-1 consensus sequence is essential for the constitutive expression of the MMP-1 gene. Aho teaches RNA isolation, reverse transcription (RT) and PCR analysis (page 504, col. 2). Figure 1 illustrates the nucleotide sequence of the 5' flanking region of the human interstitional collagenase promoter, MMP-1. Thus, since Aho has provided the sequence for the nucleic acid, Aho has inherently detected the MMP-1 containing the Ets transcription factor binding site single nucleotide polymorphism.

Conclusion

9. No claims allowable over the art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is

(571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Goldberg

Jeanine Goldberg
Patent Examiner
November 12, 2004